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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/350,518	07/09/1999	JOHN C. REED	066654-0515	8259

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SAN DIEGO, CA 92122

EXAMINER

SANG, HONG

ART UNIT	PAPER NUMBER
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1643

MAIL DATE	DELIVERY MODE
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09/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/350,518

Applicant(s)

REED, JOHN C.

Examiner

Hong Sang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-13, 16, 20-27, 32-34, 36, 37, 44 and 50-99 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-13, 16, 20-27, 32-34, 36, 37, 44 and 50-99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RE: Reed

1. Applicant's response filed on 8/1/2007 is acknowledged. Claims 11-13, 16, 20-27, 32-34, 36, 44, and 50-99 are pending. New claims 67-99 are added. Claims 1-10, 14, 15, 17-19, 28-31, 35, 37-43, and 45-49 are cancelled. Claims 16, 25, 27, 34, and 44 are amended.
2. Claims 11-13, 16, 20-27, 32-34, 36, 44, and 50-99 are under examination.

Response to Arguments

Claim Rejections - 35 USC § 102

3. The rejection of claims 11, 13, 16, 20-22, 24-27, 32, 34, 36, 44, 50-61, and new claims 67, 68, 70-73, 75-79, 81-86, 88, 89, 91, 92, 94, 95, 97 and 98 under 35 U.S.C. 102(b) as being anticipated by Turner et al. (Breast Cancer Research and Treatment (Oct. 1997), 46(1): p69, print) is maintained.

The response states that the claims, as amended, are directed to methods that include determining the level of BAG-1 expression in stage I of breast cancer. Turner et al. does not teach or suggest BAG-1 expression in stage I of breast cancer. The new claims 67-99 are directed to methods that include determining the level of BAG-1 expression in stage II of breast cancer with no lymph node involvement. Turner et al. does not teach or suggest BAG-1 expression in stage II of breast cancer with no lymph node involvement. Absent such a teaching, Turner et al. cannot anticipate new claims 67-99.

Applicants' arguments have been carefully considered but are not found persuasive. Turner et al. determined the expression of BAG-1 in benign breast epithelium (BBE), ductal carcinoma in situ (DCIS), and invasive carcinoma (IC) of the breast in 87 breast cancer patients (see abstract lines 3-5), of which 82 patients have IC and 5 patients have pure DCIS (see abstract lines 6-7). Turner et al. teach the slides were rated on a scale of intensity and % distribution within the BBE, DCIS and IC components (see lines 8-9). Turner et al. teach that the patients had a median follow-up of 13 years. Turner et al. correlated the 10-year overall survival and distant disease free survival to the overexpression level of BAG-1 in the cytoplasm and nucleus of BBE, DCIS, and IC. Because DCIS is an early stage breast cancer (no lymph node is involved), the DCIS reads on the instant stage I, and stage II with no lymph node involvement. Therefore, Turner et al. teach all limitations of the claims.

Claim Rejections - 35 USC § 103

4. The rejection of claims 11-13, 16, 20-22, 24-27, 32-34, 36-37, 44, 50-61, and new claims 67-73, 75-86, 88, 89, 91, 92, 94, 95, 97 and 98 under 35 U.S.C. 103(a) as being unpatentable over Turner et al. (Breast Cancer Research and Treatment (Oct. 1997), 46(1): p69, print) in view of Sano et al. (US patent NO. 5665539) is maintained.

The response states that Turner et al. does not teach stage I and stage II with no lymph node involvement for the same reasons given above, and Sano et al. does not cure the deficiencies of Turner et al., therefore, the claimed methods are unobvious over Turner et al. alone or in combination with Sano et al.

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Applicants' arguments have been carefully considered but are not found persuasive. The reason that Turner's reference anticipates 11, 13, 16, 20-22, 24-27, 32, 34, 36, 44, 50-61, and new claims 67, 68, 70-73, 75-79, 81-86, 88, 89, 91, 92, 94, 95, 97 and 98 has been set forth above (see paragraph 3). Therefore, the claimed methods are obvious in view of the teachings of Turner and Sano.

5. The rejection of claims 11, 13, 16, 20-22, 24-27, 32, 34, 36, 44, 50-66 and new claims 67, 68, 70-73, 75-79, 81-99 under 35 U.S.C. 103(a) as being unpatentable over Turner et al. (Breast Cancer Research and Treatment (Oct. 1997), 46(1): p69, print) in view of Sauter et al. (British Journal of Cancer, 1997, 76(4): 494-501) is maintained.

The response states that Turner et al. does not teach stage I and state II with no lymph node involvement for the same reasons given above, and Sauter et al. does not cure the deficiencies of Turner et al., therefore, the claimed methods are unobvious over Turner et al. alone or in combination with Sauter et al.

Applicants' arguments have been carefully considered but are not found persuasive. The reason that Turner's reference anticipates 11, 13, 16, 20-22, 24-27, 32, 34, 36, 44, 50-61, and new claims 67, 68, 70-73, 75-79, 81-86, 88, 89, 91, 92, 94, 95, 97 and 98 has been set forth above (see paragraph 3). Therefore, the claimed methods are obvious in view of the teachings of Turner and Sauter.

6. The rejection of claims 11, 13, 16, 20-27, 32, 34, 36, 44, 50-61, and new claims 67, 68, 70-79, 81-86, 88, 89, 91, 92, 94, 95, 97 and 98 under 35 U.S.C. 103(a) as being

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unpatentable over Turner et al. (Breast Cancer Research and Treatment (Oct. 1997), 46(1): p69, print) in view of Takayama et al. (Cancer Res. 1998, 58: 3116-3131, IDS) is maintained.

The response states that Turner et al. does not teach stage I and state II with no lymph node involvement for the same reasons given above, and Takayama et al. does not cure the deficiencies of Turner et a., therefore, the claimed methods are unobvious over Turner et al. alone or in combination with Takayama et al.

Applicants' arguments have been carefully considered but are not found persuasive. The reason that Turner's reference anticipates claims 11, 13, 16, 20-22, 24-27, 32, 34, 36, 44, 50-61, and new claims 67, 68, 70-73, 75-79, 81-86, 88, 89, 91, 92, 94, 95, 97 and 98 has been set forth above (see paragraph 3). Therefore, the claimed methods are obvious in view of the teachings of Turner and Takayama.

7. Claims 11, 13, 16, 20-22, 24-27, 32, 34, 36, 44, 50-66 and new claims 67, 68, 70-73, 75-79, 81-99 under 35 U.S.C. 103(a) as being unpatentable over Turner et al. (Breast Cancer Research and Treatment (Oct. 1997), 46(1): p69, print) in view of Love (US Patent No. 6,221,622B1, Data of Patent 4/24/2001, earliest effective filing date 4/28/1998).

The response states that Turner et al. does not teach stage I and state II with no lymph node involvement for the same reasons given above, and Love does not cure the deficiencies of Turner et a., therefore, the claimed methods are unobvious over Turner et al. alone or in combination with Love.

Applicants' arguments have been carefully considered but are not found persuasive. The reason that Turner's reference anticipates claims 11, 13, 16, 20-22, 24-27, 32, 34, 36, 44, 50-61, and new claims 67, 68, 70-73, 75-79, 81-86, 88, 89, 91, 92, 94, 95, 97 and 98 has been set forth above (see paragraph 3). Therefore, the claimed methods are obvious in view of the teachings of Turner and Love.

New Grounds of Objections

Claim Objections

8. Claims 70 and 82 are objected to because of the following informalities: Claims 70 and 80, which depend from claims 67 and 81, recite "said level of BAG-1 protein expression is determined after lymph node involvement of said cancer", however, claims 67 and 81 limit the breast cancer to only stage I and stage II with no lymph node involvement. Therefore, the claims are contradictory. Appropriate correction is required.

Conclusion

9. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hong Sang, Ph.D.

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9/12/2007

/Christopher Yaen/

Primary Examiner

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September 14, 2007